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Step Activity and 6-Minute Walk Test Outcomes When Wearing Low-Activity or High-Activity Prosthetic Feet

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Abstract

Objective—To determine changes in average daily step count (ADSC) and 6-minute walk test (6MWT) due to use of low-activity feet (LA) and high-activity energy-storage-and-return (ESAR) feet, and examine the sensitivity of these measures to properly classify different prosthetic feet.

Design—Individuals with transtibial amputations (n = 28) participated in a 6-week, randomized crossover study. During separate 3-week periods, participants wore either a LA foot (eg, solid-ankle-cushioned-heel) or an ESAR foot. Differences in 6MWTand ADSC at the end of the 3-week period were recorded.

Results—Subjects performed similarly in the 6MWT with the LA and ESAR foot (P = 0.871) and ADSC (P = 0.076). The correct classification of ESAR is only 51.9% and 61.5% with 6MWT and ADSC, respectively. For the LA foot, correct classification is less than 50% for both tests.

Conclusions—Neither ADSC or 6MWT are responsive to changes in prosthetic feet. The pitfalls and shortcomings of these instruments with regard to their ability to detect differences in prosthetic feet are outlined. Based on these results, it is not recommended that the 6MWT and ADSC are used as a means to assess outcomes for different prosthetic feet.

Keywords
Biomechanics; Amputation; Functional Testing; Walk Test; Outcome Measures

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In the most recent Cochrane Review on prosthetic ankle-foot prescription, Hofstad et al. concluded that there is currently a lack of objective measures to support prosthetic prescription. This may be guided by an inability to currently identify the best means by which to assess prosthetic rehabilitation outcomes. The criterion standard of gait assessment is considered to occur within the motion analysis laboratory setting with high-speed cameras and force plate technology. The combination of cameras and force plates can provide numerous spatial-temporal (e.g., time and distance), kinematic (e.g., joint and segmental motion), and kinetic (e.g., force, moment, power, and work) measures. The use of such a laboratory in prosthetic rehabilitation has clinical limitations owing to financial obligations and time restrictions. As a result, there has been a strong emphasis on establishing measures that are able to determine the best care for patients without the need for a motion analysis laboratory. This study will particularly focus on patients requiring the use of lower limb prostheses.

One such measure that has been translated into prosthetic rehabilitation from other pathologies is the 6-minute walk test (6MWT). The 6MWT came into existence in the early 1980s when Butland et al. showed the test was as reliable as its longer predecessor, the 12-minute walk test. It was initially used to monitor cardiac rehabilitation patients in which the primary concern was capacity for physical activity. The popularity of the 6MWT in prosthetic rehabilitation seemingly increased after it was reported to provide good classification for individuals with lower limb amputation with regard to their Medicare Functional Classification Level (MFCL). The MFCL system is the United States’ classification system that groups individuals with lower limb amputation into 5 different categories referred to as K-levels. Whereas discrimination between all the various classification levels is important for providing a prosthesis with regard to reimbursement, the most critical distinction occurs between K2- and K3-level ambulators. The Centers for Medicare Services and private insurance companies place no restrictions on the types of prosthetic feet that will be reimbursed for individuals that are classified as K3-level ambulators (with the exception of sport specific feet). The Centers for Medicare Services and private insurance companies, however, will not reimburse carbon fiber feet technology for individuals classified as K2 or lower.

The use of the 6MWT has grown in popularity as a tool to help correctly identify an individual’s MFCL status. However, the use of 6MWT to classify differences in performance due to prosthetic componentry is not supported. Gailey et al. showed no significant difference in 6MWT for a group of subjects (n = 10) wearing a prosthesis with 4 different types of feet, 2 of which were K2 level and 2 of which were K3 level. Despite their limited sample size, this study provided strong findings discouraging use of 6MWT for outcomes assessment in prosthetic rehabilitation.

More recent technological developments have resulted in the potential use of step activity monitoring to record average daily step count (ADSC) to determine functional level of individuals with lower limb amputation. Proponents of ADSC feel it gives the clinician/researcher the ability to determine an individual’s functionality outside of a laboratory setting as well as provide a functional description less prone to error from day-to-day.
variations that may influence measures captured in a single-day visit. Average daily step count uses accelerometers that are able to record the number of steps throughout the day based on acceleration spikes. Despite the early excitement and recommendations of ADSC use in prosthetic rehabilitation, studies suggest a level of futility with ADSC for prosthetic outcomes. Gailey et al.\(^8\) also recorded step counts to accompany 6MWT and found no response to changes in prosthetic feet. In fact, individuals with K2 feet took more steps on average through the day compared to the K3 feet.\(^8\) Klute et al.\(^12\) examined the effects of prosthetic knee joints on daily step activity and failed to find any significant difference between a microprocessor knee joint and a nonmicroprocessor knee joint. These findings contradict recommendations for ADSC use for outcomes assessment in prosthetic rehabilitation.

The 6MWT and ADSC have primarily been used to properly classify the individual’s functional status.\(^6,9-11,13\) However, to be an effective outcomes assessment tool, the measure needs to be responsive to different prosthetic components. Showing differences due to prosthetic components is critical, as this is the factor that is being reimbursed within the US payer system. In other words, only showing a patient has a certain functional status does not truly justify the use of certain prosthetic technologies if ultimately they will perform the same with any prosthesis and components. Therefore, the purpose of this study was 2-fold: first, to determine the impact of 2 activity levels of prosthetic feet on 6MWT and ADSC; and second, to determine the feasibility of these 2 measures (6MWT and ADSC) in distinguishing between prosthetic feet by examining the measures’ ability to properly classify each foot. It was hypothesized that despite persistent recommendations for the use of 6MWT and ADSC, these measures would not be responsive to different prosthetic feet or able to be used to differentiate prosthetic feet.

**METHODS**

**Participants**

To be included in the study, participants needed to have had their current prosthesis longer than 30 days and be able to commit to a 6-week protocol. Participants were excluded if any ulcers were present on either the residual limb or contralateral limb or if they were unable to provide informed consent owing to cognitive conditions. The presence of any major neuromuscular or musculoskeletal conditions affecting walking (eg, stroke, Parkinson disease, multiple sclerosis) would also prevent inclusion to assure the primary diagnosis afflicting the person’s ambulatory status was amputation of the lower extremity. Finally, all participants needed to be currently wearing a satisfactorily fitting endoskeletal-type prosthesis that would permit swapping prosthetic feet.

**Procedures**

Subjects participated in a randomized 6-week crossover study. Individuals were initially randomly assigned to begin wearing either a low-activity foot (LA foot; eg, solid-ankle-cushioned-heel [SACH] foot) or a high-activity energy-storage-and-return (ESAR) foot. The LA feet are either classified as having a rigid or flexible keel according to the testing and classification standards presented within the American Orthotics and Prosthetics
Association’s Prosthetic Foot Project. The ESAR feet used are all classified as dynamic keel. The Prosthetic Foot Project clearly states that the measurement and categorization of the mechanical properties of the feet does not constitute clinical standards or effectiveness of the prosthetic feet when applied to specific patients. The Prosthetic Foot Project does, however, provide mechanical properties of the feet, which is then used to assign payer codes. Prosthetic feet with rigid or flexible keel classification are designed to be prescribed for functional levels K2 or lower; a dynamic keel classification is designed to be prescribed for functional levels K3 or higher. These distinct mechanical classification and functional classification differences guaranteed mechanical and clinical differences in components being worn by subjects. After assignment of the subject to either the LA or ESAR foot, the subjects’ current prosthetic foot was removed and replaced. The patient’s height, weight, and residual limb length were used to appropriately select the LA and ESAR foot for each subject. The subject’s socket and suspension previously prescribed and fabricated by their prosthetist was used to mitigate confounders from socket fit and suspension. The prosthesis was then properly aligned by a certified prosthetist. A step activity monitor was attached to the subject’s pylon and covered in a binding material to prevent dislocation. The subject then wore the prosthesis for 3 weeks, coming to the laboratory every 1.5 weeks to download data and recharge the monitor. At the end of the initial 3-week wear period, subjects performed a 6MWT. During the 6MWT, subjects were not given encouragement, as this can substantially affect total distance walked. After the 6MWT, the prosthetic foot was switched and another 3-week period was repeated with the same protocol. Importantly, the prosthesis was properly aligned again, after the foot was switched by the same prosthetist. During each 3-week period, participants were given no specific instructions for activity.

The ADSC was recorded for each 3-week period excluding the days the person came to the laboratory. Participants were subjected to other tests on the days they were in the laboratory as part of additional studies; and as a result, these days did not reflect their typical activities of daily living. These studies’ findings are reported elsewhere. Differences in ADSC for the different prosthesis setups and total distance for the 6MWT were tested through a dependent t test with an alpha level set to 0.05, and the corresponding 95% confidence intervals were calculated. Profile and agreement plots were generated as visualizations of the agreement between the measures taken under differing setups. A generalized linear mixed model for a binary outcome with logit link was used to summarize the classification ability of these tests while accounting for the correlation due to measurements on the same individual. Prosthesis was the dependent variable with separate models fit for 6MWT and ADSC as the independent variable.

RESULTS

Twenty-eight individuals with transtibial-level amputation provided written consent according to University Medical Center Institutional Review Board–approved protocol procedures. Twenty-four of the participants were unilaterally affected, whereas 4 had bilateral transtibial level amputations (Table 1). All individuals were previously classified by their physician and prosthetist as K3- or K4-level ambulators (ie, high activity, community

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Actigraph, 49 East Chase St, Pensacola, FL 32502
ambulators, capable of various walking speeds). Subjects’ prescribed prosthetic feet were consistent with this classification (Table 2). Average daily step count (ADSC) could only be obtained from 26 subjects owing to malfunction of the monitor. One individual refused to complete the 6MWT. For the 6MWT, individuals showed no significant difference in walking distance when walking with a LA foot or an ESAR foot ($P = 0.871$; 95% confidence interval: −17.5 to 20.5 m; Table 3). Results for ADSC were similar. The ADSC showed no significant difference when walking with the higher-activity ESAR foot compared to the LA foot ($P = 0.076$; 95% CI, −33.7 to 623.8 steps). As shown in the profile and agreement plots, measures were nearly identical for most participants under both conditions (Figs. 1, 2). The heterogeneity of ESAR feet prevented any notable trends specific within any make or model of ESAR feet. Figure 3 depicts the predicted probability of being classified as ESAR by using the 6MWT or ADSC measure, and is plotted against its respective measure from which the probability is calculated (ie, either 6MWT or ADSC). If either were good classification tools, we would begin to see some separation between symbols with increase in the independent variable. However, as clearly shown in Figure 3, there is no separation of devices based on 6MWT and ADSC. Using a cutoff probability of 0.5, the correct classification of ESAR is only 51.9% and 61.5% with 6MWT and ADSC, respectively. For the LA Foot, correct classification is less than 50% for both tests.

**DISCUSSION**

Despite previous work showing differences in activity level of patients when measuring either 6MWT or ADSC, this was not the case for changes in the prosthetic foot. This is concerning, as the prosthetic foot represents a major component of a prosthesis, both in functionality and cost. If neither measure is responsive to changes with a major component, it is doubtful that smaller componentry would warrant any response thereby questioning the value of these measures in prosthesis outcomes assessment. In the current study, neither measure was adequate to distinguish prosthetic feet; measurements were nearly identical for most subjects under both conditions (Fig. 1). Whereas results for ADSC may be approaching significance, it should be noted that ADSC was greater when participants wore the LA feet, consistent with Gailey et al. From Figures 1 and 2, it is noted that there is a nearly equal split with regard to some individuals increasing their ADSC and 6MWT with the use of ESAR feet, whereas some decreased. Because of this, we would not expect any cumulative effect to influence the results such that perhaps a 12-minute walk test would have different results. However, this was not tested. Based on the current results, ADSC would make it more difficult to justify the use of more expensive carbon fiber feet in K3-level patients, as it may promote decreased activity. This conclusion would seem counter to clinical impressions from such feet.

The prosthesis, or specifically within this study, the prosthetic foot, is a mechanical device attempting to replace the biomechanics of the amputated limb. There are multiple influences beyond the characteristics of the prosthesis that can affect the 6MWT and ADSC. Included in these considerations are physical fitness and self-efficacy, as evidenced by the initial body of work using the 6MWT in cardiac rehabilitation and obesity. Ultimately, the problem with the 6MWT and ADSC for prosthesis outcomes assessment may be the global nature by which the task is accomplished. There are many factors (eg, strength, range of motion,
neuromuscular control, cardiovascular reserve, motivation, biomechanics of the person and prosthesis, etc.) that affect the task of movement. With so many factors affecting performance, individuals can reweight and rely more heavily on other factors in the presence of any deficiencies. A prosthesis only directly changes the biomechanics. Hence, if an LA foot is used on a high-activity individual, they can use more of the available strength and range of motion to potentially increase compensations. They are more likely to have the available neuromuscular control to manage to quickly adapt and accomplish the task. As a result, the impact of the prosthesis may not be detected by the 6MWT and ADSC. It thus needs to be considered what is being measured and what we as prosthetists desire to measure. A prosthetist is trained to fit a prosthesis, and then perform observational gait analysis, followed by realignment to alter the biomechanics of the prosthesis to minimize gait deviations. This overly simplified process should be the root of any attempt at outcomes assessments. In other words, we need to consider what are the most pervasive gait deviations and altered biomechanics and attempt to record these outcomes. There should be focus on assessing quality of gait, not quantity. Prosthetists have known for decades that these are the end points of concern, yet we are seeing increased recommendations of measures that do not directly measure gait deviations and altered biomechanics. Biomechanics are not measured by 6MWT and ADSC. As an example, consider the lone subject that refused to do 6MWT. The subject had a body mass index of 44.3, was considered morbidly obese, and was also a smoker. Walking from the parking lot to the laboratory required breaks for this person. These details all highlight the subject’s poor physical fitness. However, when the subject performed detailed gait analysis, the lower limb joint moments and joint powers were consistent with the other participants in the study, which were also K3-level ambulators. In this subject’s case, physical fitness and self-efficacy are limiting factors in the 6MWT, and the mechanics of the prosthetic foot are not a factor. This person was able to ambulate with variable cadence, a key descriptor for Medicare K3-level classification. In addition, she is a “community ambulator who has the ability to traverse most environmental barriers” and has vocational activities that require prosthetic use beyond simple walking. Yet, if we were to endorse the use of 6MWT, this patient would not have qualified for the higher-technology prosthetic foot she uses.

Even more problematic may be the use of ADSC. A person’s activity through the day is largely dictated by that person’s routine. If an individual awakes in the morning and performs their daily routine, a device will have minimal effect on changing the person’s desire to do this. Changing the prosthesis will change the biomechanics of the individual. More specifically, the prosthetic foot can affect step length. If an individual has a certain routine through the day, the individual walks the same distance each day as part of the routine. The step length afforded by the mechanics of the prosthetic foot will dictate how many steps are needed to cover that same distance. An example of this is the bilateral subject that participated in this study whose K3 feet were the only currently commercially available powered ankle-foot system. The primary mechanical difference in this powered ankle-foot system is its increased ankle power output in late stance during push off. Beyond that, the foot is built on a traditional ESAR foot platform (Variflex).
result, other benefits of ESAR feet should be expected as well.\textsuperscript{23,24} A major noted finding of ESAR feet over LA feet such as SACH is the late-stance energy return (hence the acronym ESAR).\textsuperscript{14} Thus, from a mechanical perspective, the ankle-foot system represents an ESAR foot with an increased positive energy profile in late stance, further exaggerating known mechanical differences between ESAR and SACH feet used in this study for purposes of improving the ability to detect differences. The individual’s ADSC when wearing the powered ankle-foot system was 4,432.2 steps, but when wearing bilateral SACH feet, he averaged 4,973.4 steps per day. Yet, in the detailed gait analysis as part of the larger study, the subject’s step length when wearing bilateral SACH feet was, on average, 0.592 m but 0.699 m for the powered ankle-foot system. Using rough approximations, this would indicate that the subject covered approximately 2,944.3 m/d when wearing the bilateral SACH but 3,098.1 m/d for the bilateral powered ankle-foot system. Despite limitations with this generalized calculation, this distance covered does support increased activity with a higher activity foot. Therein lies not only the major limitation of ADSC but also the possible erroneous conclusions that could be drawn by simply looking at the number of steps taken in a day. Average daily step count does not account for quality of gait. The inclusion of patient’s step length may improve results from ADSC, or, alternatively, step activity monitors are being equipped now with the ability to determine different activities based on pattern recognition algorithms, which may also provide more responsive outcomes assessments.

It should be noted that this study enrolled individuals that were K3-/K4-level ambulators for ease of recruitment, and then “downgraded” the patients to a lower–activity level foot component. These results, however, should not necessarily be considered applicable in the scenario of a lower-level ambulator that is using a higher activity level foot component. In particular, the results noted within this study may actually be highlighting a ceiling effect for 6MWT and ADSC whereby the positive impact of high-activity feet may not be a large enough factor to deter daily activity of K3-/K4-level ambulators. On the other hand, the positive attributes of high-activity feet may be enough to motivate increased daily activity detectable via 6MWT and ADSC among lower-level ambulators. This will need to be further explored. Consistent with previous discussion, it is possible that low-level ambulators do not have the available resources (eg, strength, range of motion, neuromuscular control, cardiovascular reserve, motivation, etc.) to effectively reweigh such factors and overcome deficiencies and need every bit of added biomechanical advantage from ESAR feet.\textsuperscript{23}

Finally, there is the possibility that the reason the ADSC and 6MWT were not sensitive enough to detect a difference between the prosthetic feet may reflect an actual lack of differences. It seems unlikely given the body of literature that supports ESAR feet over simpler feet such as SACH feet, but it is a possibility worth considering. However, this may be a limitation of the study population, which was entirely composed of K3 or higher ambulators. By definition, these individuals are more active and it is possible that these participants were able to compensate and overcome deficits imposed by the lower-activity foot. Future work should expand to examine K2 ambulators.

\textsuperscript{d}Ossur, 27051 Towne Centre Dr, Foothill Ranch, CA 92610
Study Limitations

There are limitations to this study. First, the timeframe under which subjects were monitored for ADSC needs to be considered. Three weeks was chosen as the period because this has been outlined as an adequate adaptation period, and thus, it was felt that the measure of the 6MWT at the end of such a period would overcome the limitation of adaptation. This, however, does not exclude ADSC from being influenced by adaptation or learning, as the individual may have experienced more dramatic changes through the 3-week period depending on the device, which could influence the outcomes. However, the use of an initial 3-week period has clinical attractiveness because it falls under the 30-day trial period that many prosthetic foot manufacturers offer on prosthetic feet purchases. Three weeks is also likely not long enough for biomechanical differences in prosthetic components to influence other factors such as physical fitness and self-efficacy, which may lead to improved response in 6MWT and ADSC. It should be noted though that Gailey et al. used an 8-week period and failed to find differences. This raises the questions of how long a time period would be necessary to see differences in ADSC or 6MWT due to prosthesis difference, and if such a period would be pertinent to prosthetic rehabilitation where the typical prosthesis has a 3-year warranty and then should be considered for replacement for safety reasons to prevent failure.

Furthermore, all participants had a history of prosthetic use, and it is unclear what impact their experience with previously using ESAR feet may have had on the current findings. However, it would seem that this would negatively influence their performance on the foot that was least like the foot they had more experience using, but results showed performance on the LA feet were similar to the ESAR feet according to ADSC and 6MWT. Next, we assumed that the manufactured feet are characterized correctly, such that the ESAR feet are truly “higher activity”. The ESAR feet are classified as dynamic response type of feet with a skeleton of carbon fiber (or similar material with high passive energy return properties). It is possible these feet are not truly higher-activity level, although this would seem to be more of a nomenclature problem and perhaps the feet should be more appropriately described by their mechanical properties such as energy return.

In addition, we used multiple make and models of ESAR feet to best accommodate patient weight and limb length. This heterogeneity within ESAR feet prevented any possible trends of performance specific to any manufacturer or specific model. Additionally, this study relied on classification of patients according to MFCL. It seems more reasonable that the millions of individuals with amputation would fall into a spectrum of functional or activity levels. For example, the ADSC for the 27 individuals in this study had a range of average steps from 2,393.6 to 9,626.1. Additionally, whereas the accelerometer has shown good reliability for step count detection, step counts are based on accelerations for nonprosthetic ambulation. Increased accelerations may be possible with prosthetic ambulation causing artifacts in step count calculation.

Finally, walking speed continues to gain popularity as an outcome measure. Walking speed was not included as an outcome measure in this study, although it may have been more sensitive than ADSC and 6MWT. However, walking speed will factor into 6MWT, and the pervasive lack of differences in 6MWT would not lend itself to the thought that walking
speed would detect differences in a population that will not be as hindered by fatigue as lower-level ambulators. This should be tested in future work comparing feet, however, before any conclusions are made.

CONCLUSION

The use of 6MWT and ADSC may provide good descriptions of a lower limb prosthesis user’s functional ability. However, these measures do not account for many factors that go into an individual’s functionality. As such, in the case of prosthetic rehabilitation, the prosthetic foot type does not affect the 6MWT and ADSC for K3-/K4-level ambulators despite known differences in LA and ESAR feet. Failure to account for the biomechanical function of prosthetic feet yields a lack of differences in 6MWT or ADSC or, even possibly, results that could lead to detrimental interpretation. Clinicians are cautioned against using 6MWT and ADSC to assess prosthetic outcomes for K3-/K4-level ambulators.

Acknowledgments

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References


FIGURE 1.
Profile plots for 6MWT (A) and ADSC (B).
FIGURE 2.
Agreement plots for 6MWT (A) and ADSC (B).
FIGURE 3.
Predicted probability of ESAR based on 6MWT (A) and ADSC (B).
### TABLE 1

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<th>Age (yrs)</th>
<th>Height (cm)</th>
<th>Mass (kg)</th>
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<th>Residual Limb Length (cm)</th>
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All participants were above MFCL K2 level. Mean ± SD.
TABLE 2

Models of prosthetic feet prescribed to each patient, as well as the feet used within the study

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<td>Axtion\textsuperscript{g}</td>
<td>SACH\textsuperscript{c}</td>
<td>Renegade\textsuperscript{e}</td>
</tr>
<tr>
<td>26</td>
<td>Sure-flex\textsuperscript{d}</td>
<td>SACH\textsuperscript{c}</td>
<td>Elite\textsuperscript{b}</td>
</tr>
<tr>
<td>27</td>
<td>Catalyst\textsuperscript{h}</td>
<td>SACH\textsuperscript{c}</td>
<td>Senator\textsuperscript{e}</td>
</tr>
<tr>
<td>28</td>
<td>Trustep\textsuperscript{f}</td>
<td>SACH\textsuperscript{c}</td>
<td>C-Walk\textsuperscript{e}</td>
</tr>
</tbody>
</table>

All LA feet are either rigid or flexible keels, ESAR feet are dynamic keels.\textsuperscript{14}

\textsuperscript{†}Subject’s initial use of prescribed foot coincided with study, subject had no prior experience with the foot.

\textsuperscript{†}The Walktek is classified as Flexible keel whereas the SACH is Rigid.

\textsuperscript{b–j}Refer to the Supplier list.
<table>
<thead>
<tr>
<th></th>
<th>LA Foot</th>
<th>ESAR Foot</th>
<th>% Correct Classification ESAR</th>
<th>% Correct Classification LA Foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>6MWT, m</td>
<td>424.2 ± 21.1</td>
<td>422.7 ± 18.2</td>
<td>51.9</td>
<td>40.7</td>
</tr>
<tr>
<td>ADSC, daily steps</td>
<td>4955.0 ± 437.8</td>
<td>4660.0 ± 349.3</td>
<td>61.5</td>
<td>46.2</td>
</tr>
</tbody>
</table>

There were no significant differences between LA* and ESAR* level feet for either measure (α = 0.05).

Mean ± SE.

* Classification based on Medicare Functional Classification Level system.